# CERTIFIED FOR PUBLICATION

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IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

## THIRD APPELLATE DISTRICT

(Sacramento)

SAVIENT PHARMACEUTICALS, INC.,

Plaintiff and Appellant,

C050171

Sup.Ct. No. 04CS00084)

v.

DEPARTMENT OF HEALTH SERVICES et al.,

Defendants and Respondents,

RAMSELL CORPORATION,

Real Party In Interest and Respondent.

APPEAL from a judgment of the Superior Court of Sacramento County, Raymond M. Cadei, Judge. Reversed with directions.

Richard M. Ross for Plaintiff and Appellant.

Bill Lockyer, Attorney General, Thomas R. Yanger, Senior Assistant Attorney General, Joseph O. Egan and Michael V. Hammang, Deputy Attorneys General, for Defendants and Respondents.

Collette, Erickson, Farmer & O'Neill, William S. Farmer and John J. O'Neill for Real Party In Interest and Respondent.

Savient Pharmaceuticals, Inc. (Savient) challenges the structure and actions of a Department of Health Services program administered by Ramsell Corporation (Ramsell).

"The AIDS epidemic was and continues to be one of the most dangerous of the modern era, killing over half a million Americans as of the end of 2003. Despite the introduction of antiretroviral therapy, AIDS remains the fifth leading cause of death among those ages 25 to 44. Sadly, HIV mortality declines have slowed while, at the same time, AIDS diagnoses have risen." (John B. v. Superior Court (2006) 38 Cal.4th 1177, 1195.)

HIV infection "can be a manageable, though chronic condition with the use of drugs[,]" and for "reasons of compassion and cost effectiveness, the State of California has a compelling interest in ensuring that its citizens infected with the HIV virus have access to these drugs." (Health & Saf. Code, § 120950, subds. (a)(b); further unspecified section references are to this code.)

"The AIDS Drug Assistance Program (ADAP), within the [Department], was established in 1987 to help ensure that HIV-positive uninsured and under-insured individuals have access to pharmaceutical (drug) therapies. . . . Without the drugs available through ADAP, thousands of HIV-positive Californians would face rapidly deteriorating health." (DHSS, Aids Drug Assistance Program -- ADAP Fact Sheet (Oct. 2005) at www.dhs.ca.gov/AIDS.)

The Department subsidized some drugs for some people, but federal budget decisions threatened the program. (§ 120950, subds. (c)-(e).) Accordingly, in 1995 the Legislature adopted a new mechanism whereby the Department maintains a list of drugs to be dispensed (the ADAP formulary) and collects manufacturer

rebates to fund the program. (§§ 120955, 120956; Stats. 1995, ch. 415, § 7.)

Savient makes Oxandrin, a drug used to treat weight loss. In 2003 the Department restricted it to use in females, because of cheaper drugs "for treatment of HIV-related wasting in males." We refer to this as a delisting, although Oxandrin remains listed for some uses.

Savient filed a petition for writ of mandate and declaratory relief to invalidate the delisting and to nullify the Department's contract with Ramsell. The trial court rejected all of Savient's claims and Savient timely appealed.

Although we reject most of Savient's claims, we agree that the ADAP formulary is a regulation subject to the Administrative Procedures Act (Gov. Code, § 11340 et seq., APA). Accordingly, we reverse with directions.

#### FACTUAL AND PROCEDURAL BACKGROUND

Savient's amended petition sought to undo Oxandrin's delisting and compel the adoption of regulations governing the formulary. Savient sought refund of "all rebates" collected under the program and an order "to set aside any contracts delegating any portion of the administration" of the program. Savient sought a declaration of the lawfulness of the Department's actions in administering the formulary and in contracting with Ramsell. Savient raised numerous theories, miscaptioned as 11 purported "causes of action."

The answers of the Department and Ramsell questioned Savient's standing and defended the program.

The Department's answer tendered the declaration of Celia Banda-Brown, a "Health Program Specialist I" whose duties include "primary liaison to the ADAP Medical Advisory Committee (MAC)" and managing the formulary. Because Savient did not tender contrary facts, we accept as true the facts stated in her declaration.

The ADAP program was created in 1987 and is separate from Medi-Cal, "with different eligibility criteria and benefits, including distinct drug formularies." Funding "comes from the state's general fund, the federal Ryan White Care Act and rebates paid by drug manufacturers, as required by section 120955(d)." Except for a few statutory mandates (such as to provide antiretroviral drugs), "there is no other state or federal requirement for specified drugs [or] classes of drugs to be provided on the ADAP formulary. On the other hand, Medi-Cal must cover all FDA-approved drugs."

The MAC evaluates AIDS drugs and recommends changes to the formulary, including "any restrictions or medical access criteria;" these recommendations, combined with a departmental fiscal analysis, inform the Department director when she or he makes changes to the formulary. "Because California ADAP is not an entitlement program, it must provide drugs within an existing budget and assure sufficient funds are available before adding any new drug to the formulary. Therefore, given this budgetary criteria, a drug may be recommended by the MAC yet never make it on the formulary due to cost constraints or because other drugs have a higher [medical] priority (e.g., antiretrovirals). There

are currently 153 drugs on the ADAP formulary . . . and over 27,000 ADAP clients who access these drugs annually."

Oxandrin was added to the formulary in 1998, "restricted to use by women and persons with liver disease," "due to the high cost of the drug and the availability of other, less expensive anabolic steroids for treatment of HIV-related wasting in males." In 1999 the program budget increased and the restrictions were removed. By 2003, due to increased client demand, a projected "funding shortfall, and the recent availability of a new but very high cost antiretroviral drug," the MAC recommended reinstating the restrictions, which was done. The decision was made based on the MAC recommendation "and the fiscal analysis by the department. The department's contractor, Ramsell Corporation did not have any involvement in the analysis or decision-making leading to the restriction of the drug. Furthermore, Ramsell Corporation exercises no discretion concerning what drugs are on the ADAP formulary, the criteria for determining eligibility of ADAP recipients, pricing of drugs or any aspect of the rebate program between the Department and the drug manufacturers."

After a hearing the trial court denied relief on all legal theories. Savient timely appealed from the ensuing judgment.

## THE PRINCIPAL STATUTE

Section 120955 provides in part as follows:

"(a)(1) To the extent that state and federal funds are appropriated in the annual Budget Act for these purposes, the director shall establish and may administer a program to provide drug treatments to persons infected with human

immunodeficiency virus (HIV), the etiologic agent of acquired immune deficiency syndrome (AIDS). . . .

- "(2) The director shall develop, maintain, and update as necessary a list of drugs to be provided under this program.
- "(b) The director may grant funds to a county public health department through standard agreements to administer this program in that county. . . .
- "(c) The director shall establish a rate structure for reimbursement for the cost of each drug included in the program. Rates shall not be less than the actual cost of the drug. However, the director may purchase a listed drug directly from the manufacturer and negotiate the most favorable bulk price for that drug.
- "(d) Manufacturers of the drugs on the list shall pay the department a rebate equal to the rebate that would be applicable to the drug under . . . the federal Social Security Act . . . plus an additional rebate to be negotiated by each manufacturer with the department, [with exceptions].
- "(e) The department shall submit an invoice, not less than two times per year, to each manufacturer for the amount of the rebate required by subdivision (d).
- "(f) Drugs may be removed from the list for failure to pay the rebate required by subdivision (d), unless the department determines that removal of the drug from the list would cause substantial medical hardship to beneficiaries.
- "(g) The department may adopt emergency regulations to implement amendments to this chapter made during the 1997-98 Regular Session, in accordance with the Administrative Procedure Act, Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. The initial adoption of emergency regulations shall be deemed to be an emergency and considered by the Office of Administrative Law as necessary for the immediate preservation of the public peace, health and safety, or general welfare. Emergency regulations adopted pursuant to this section shall remain in effect for no more than 180 days.

- "(h) Reimbursement under this chapter shall not be made for any drugs that are available to the recipient under any other private, state, or federal programs, or under any other contractual or legal entitlements, except that the director may authorize an exemption from this subdivision where exemption would represent a cost savings to the state.
- "(i) The department may also subsidize certain cost-sharing requirements for persons otherwise eligible for the AIDS Drug Assistance Program (ADAP) with existing non-ADAP drug coverage . . . "

#### DISCUSSION

- I. Failure to Issue a Declaration of Rights
  Savient first complains that the trial court failed to
  declare the rights of the parties. A plaintiff is entitled to a
  declaration of rights, even if the declaration is that the
  plaintiff has no rights as asserted in the complaint. (Western
  Aggregates, Inc. v. County of Yuba (2002) 101 Cal.App.4th 278,
  305.) However, an appellate opinion memorializes the rights of
  the parties and Savient's procedural point, of itself, provides
  no basis for reversal. (See Haley v. L. A. County Flood Control
  Dist. (1959) 172 Cal.App.2d 285, 292-294.)
- Savient asserts the Department improperly delegated management to Ramsell. The Department asserts Savient lacks standing to make this claim.

Delegation of Authority to Ramsell

Savient asserts that the trial court's ruling on demurrer, finding it had stated some good causes of action, either precludes the Department from challenging standing or means that the Department had to file a cross-appeal. First, the

respondent has the right to defend a favorable judgment without filing a cross-appeal. (See 9 Witkin, Cal. Procedure (4th ed. 1997) Appeal, § 612.) Second, Savient's failure to cite authority forfeits the contention that standing cannot now be considered. (People v. Gidney (1937) 10 Cal.2d 138, 142-143 (Gidney).) Accordingly, we reach the standing question.

"[S]tanding to seek a writ of mandate ordinarily requires that a party be 'beneficially interested' (Code Civ. Proc., § 1086), i.e., have 'some special interest to be served or some particular right to be preserved or protected over and above the interest held in common with the public at large.' [Citation.] This standard, we have stated, 'is equivalent to the federal "injury in fact" test, which requires a party to prove by a preponderance of the evidence that it has suffered "an invasion of a legally protected interest that is [both] '(a) concrete and particularized, and (b) actual or imminent . . . . '"'" (People ex rel. Dept. of Conservation v. El Dorado County (2005) 36 Cal.4th 971, 986.)

The evidence shows that the Department delisted Oxandrin.

Nothing done by virtue of the Ramsell contract hurt Savient.

Because the contract did not specially aggrieve Savient, it

lacks standing to attack the contract. (See Sacramento County

Fire Protection Dist. v. Sacramento County Assessment Appeals

Bd. (1999) 75 Cal.App.4th 327, 331-332 (SCFPD).) Savient does

not claim that any exception to this general rule applies (i.e.,

the "public interest exception" or taxpayer standing, cf.

California State Employees' Assn. v. Williams (1970) 7

Cal.App.3d 390 395 {Williams}) and has therefore forfeited any

such claim. (Gidney, supra, 10 Cal.2d at pp. 142-143; In re

Marriage of Nichols (1994) 27 Cal.App.4th 661, 672, fn. 3.) In

any event, "[T]here is no pressing need for [Savient] to have

standing here. This is not a situation where the issue raised . . . will be removed from judicial review if standing is denied." (SCFPD, supra, 75 Cal.App.4th at pp. 333-334.)

However, we will briefly address and reject Savient's claims on the merits.

## A. Statutory Authorization

Savient asserts, "The [L]egislature did NOT authorize Respondents to contract ADAP's civil service jobs to private contractors." Apart from the civil service question we will discuss in a moment, we reject Savient's claim that the Department lacked legislative authority to contract with Ramsell.

Section 120970 provides that certain conditions would apply "In the event the Department utilizes a contractor or subcontractor to administer any aspect of the program provided for under this chapter[.]" Thus, the Legislature expressly contemplated that the Department might elect to contract with an outside entity to administer some aspects of the program, specifically "obtain and dispense the necessary drugs, in their approved forms according to the program formulary," process changes to the formulary within 10 business days, verify prompt delivery of drugs to clients and so forth. (§ 120970, subds. (a)-(k).)

Savient points to a different statutory provision which allows the Department to "grant funds to a county public health department through standard agreements to administer this program in that county." (§ 120955, subd. (b).) Savient

asserts that this provision precludes the Department from contracting with a private entity. We disagree. That provision authorizes the transfer of state funds to a county, under specified conditions. Section 120970 contemplates administration of the program by a contractor, a private entity. We see no overlap or conflict between these two provisions.

## B. Civil Service Mandate

Savient claims the Department violated the civil service mandate (Cal. Const, art. VII) by allowing Ramsell to undertake work which Savient asserts should be done by public employees. We disagree.

The relevant provisions of the California Constitution do not explicitly prohibit contracting out, but do so by implication. (Consulting Engineers & Land Surveyors of Cal., Inc. v. Professional Engineers in Cal. Govt. (2006) 140

Cal.App.4th 466, 471; California State Employees' Assn. v. State of California (1988) 199 Cal.App.3d 840, 844.) However, there are exceptions, as explained in Professional Engineers v.

Department of Transportation (1997) 15 Cal.4th 543, at pages 548-549:

"Because of the largely implicit nature of the private contracting restriction, we must discern its scope from judicial decisions applying it in particular cases. Early appellate decisions held that the civil service mandate forbids private contracting, whether for permanent or temporary services, skilled or unskilled, if those services are of a kind that persons selected through civil service could perform 'adequately and competently.' [Citations.]

"Later cases have affirmed the 'nature of the services' restriction . . . but have also indicated that the restriction is inapplicable if the state seeks to contract for private assistance to perform new functions not previously undertaken by the state or covered by an existing department or agency. [Citations.] As [Williams, supra, 7 Cal.App.3d 390] observed, '. . . if the services cannot be adequately rendered by an existing agency of the public entity or if they do not duplicate functions of an existing agency, the contract is permissible.' [Citation.] According to Williams, the civil service mandate is aimed at protecting 'the existing civil service structure,' and does not compel the state 'to fulfill every new state function through its own agency.'" (Original italics.)

Savient acknowledges that the civil service mandate does not cover new state functions, but argues that because the Department managed the program from 1987 until 1997, the program thereby became an historic state function. We disagree. Savient has not provided any evidence that the provision of drugs is an historic state function, and the mere fact that the state performed such function for "a few years," as Savient states in its brief, does not make it an historic state function.

The key in such cases is whether a contract displaces the civil service. (See Department of Transportation v. Chavez (1992) 7 Cal.App.4th 407, 414 (Chavez); Williams, supra, 7 Cal.App.3d at p. 399.) Savient offers no evidence that the contract here had such effect.

Indeed, the Legislature has provided a mechanism to police encroachments on the civil service. (Gov. Code, §§ 19130, subd. (b)(2), 19132; see *Chavez*, *supra*, 7 Cal.App.4th at pp. 414-417.) Apparently, nobody litigated the question now at issue and, as just stated, if there is any evidence that civil servants were

displaced by the contract, Savient failed to adduce it in this proceeding.

C. Scope of Delegation

Savient complains that the Department delegated too much authority to Ramsell. We disagree.

Savient agrees that "ministerial or administrative functions" may be delegated. (See Sacramento Chamber of Commerce v. Stephens (1931) 212 Cal. 607, 610.)

Ramsell is required by statute to administer grievance procedures (§ 120970, subd. (k)) and the evidence shows Ramsell "exercises no discretion concerning what drugs are on ADAP formulary, the criteria for determining eligibility of ADAP recipients, pricing of drugs or any aspect of the rebate program between the Department and the drug manufacturers." Therefore, we reject Savient's factually bereft claims that improper delegation occurred.

III. The Formulary is a Regulation
A critical purpose of the APA is:

". . . to establish basic minimum procedural requirements for the adoption, amendment, or repeal of administrative regulations. Except as provided in Section 11346.1, the provisions of this chapter are applicable to the exercise of any quasi-legislative power conferred by any statute heretofore or hereafter enacted, but nothing in this chapter repeals or diminishes additional requirements imposed by any statute. This chapter shall not be superseded or modified by any subsequent legislation except to the extent that the legislation shall do so expressly." (Gov. Code, § 11346, subd. (a).)

Under the APA a regulation is "every rule, regulation, order, or standard of general application or the amendment,

supplement, or revision of any rule, regulation, order, or standard adopted by any state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure." (Gov. Code, § 11342.600.) "No state agency shall issue, utilize, enforce, or attempt to enforce any guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule, which is a regulation as defined in Section 11342.600, unless" it has been adopted in compliance with the APA. (Id., § 11340.5, subd. (a).)

As stated, section 120955, subdivision (a)(2) provides: "The director shall develop, maintain, and update as necessary a list of drugs to be provided under this program." Savient contends the formulary is a regulation subject to the APA. We agree with Savient.

In a written ruling the trial court found that cases cited by Savient did not directly support application of the APA to the formulary and concluded: "In light of the lack of any such direct authority, as well as the fact that changes to the Medi-Cal formulary now are explicitly exempt from the APA [Welf. & Inst. Code, § 14105.39, subd. (g)], and that the applicable statute regarding the ADAP formulary does not explicitly require APA compliance [§ 120955, subd. (a)(2)]... respondent's actions in this case were not required to be accomplished through an APA rule-making procedure."

The trial court thus gave three reasons for rejecting Savient's initial claim that the APA could apply to the ADAP

formulary: (1) there was no case on point; (2) the ADAP statutes did not explicitly require APA compliance; and (3) the Medi-Cal formulary does not have to be changed through the APA because of an explicit exemption.

The first and second reasons lack persuasive force because the APA does not have to be referenced in a statute or adjudicated by case law before it applies: It applies generally to any regulation meeting the APA definition, absent an exemption. (Gov. Code, § 11346; Voss v. Superior Court (1996) 46 Cal.App.4th 900, 909; Engelmann v. State Bd. of Education (1991) 2 Cal.App.4th 47, 58-59.)

On appeal Savient persists in its assertion that there is direct authority for its position that a drug formulary is a regulation. Savient's reliance on California Medical Assn. v. Brian (1973) 30 Cal.App.3d 637 (Brian) is, as the trial court carefully explained, misplaced. A close reading shows that in Brian we invalidated Medi-Cal consultant "guidelines" based on the APA, not changes to the drug formulary which were also discussed. (Id. at pp. 654-655.)

The third reason cited by the trial court helps persuade us in the other direction. The trial court was persuaded that the Medi-Cal formulary was analogous to the ADAP formulary and because the Medi-Cal formulary could be amended without APA compliance, so too could the ADAP formulary. But the reason the Medi-Cal formulary can be amended without APA compliance is

because of a statutory exemption. (Welf. & Inst. Code, § 14105.39, subd. (g).) No such exemption exists regarding the ADAP formulary.

We also observe that the principal statute contains an APA exemption for "emergency regulations to implement amendments to this chapter made during the 1997-98 Regular Session[.]" (§ 120955, subd. (g).) An exemption would be unnecessary if the APA did not apply. The trial court was of the view that this provision pertained solely to the rebate structure but even if that is correct, that does not change the fact that the Legislature assumed the APA applied to the principal ADAP statute.

Having rejected the view that the APA does not apply generally, we now address the central question at hand. The trial court concluded "[t]he formulary does not establish a rule of general application, or interpret or make specific the law the DHS Director is to administer, or govern the agency's procedure. Instead, it is a list of available products established in the exercise of the DHS Director's statutory discretion." The Department, too, asserts the formulary is merely a "list" which its director has "power and discretion" to develop. Savient claims the formulary is a regulation because it makes specific the law administered by the Department. Savient has the better claim.

"The APA . . . defines 'regulation' very broadly to include 'every rule, regulation, order, or standard of general application . . . adopted by any state agency to implement, interpret, or make specific the law enforced or

administered by it, or to govern its procedure, except one that relates only to the internal management of the state agency.' [Citation.] A regulation subject to the APA thus has two principal identifying characteristics. [Citation.] First, the agency must intend its rule to apply generally, rather than in a specific case. The rule need not, however, apply universally[.] . . . Second, the rule must 'implement, interpret, or make specific the law enforced or administered by [the agency], or . . . govern [the agency's] procedure.'" (Tidewater Marine Western, Inc. v. Bradshaw (1996) 14 Cal.4th 557, 571.)

To reiterate, section 120955, subdivision (a)(2) provides:
"The director shall develop, maintain, and update as necessary a
list of drugs to be provided under this program." That list by
definition reflects the director's determination of which drugs
will be provided by the program. That is a rule of general
application which makes specific the ADAP law. The formulary
therefore falls within the APA definition of a regulation.

The Department's repeated emphasis on the fact that the statute confers "discretion" on the director when choosing to amend the formulary misses the point. We agree that changing the formulary reflects a policy determination within the director's discretion. (See *Upjohn Co. v. Ohio Dept. of Human Serv.* (1991) 77 Ohio App.3d 827, 832-833 [603 N.E.2d 1089, 1093] [decision to remove drug from state Medicaid formulary "an executive policymaking function involving the exercise of a high degree of official judgment and discretion"].) As just explained, that policy decision makes specific the law administered by the Department, meeting the broad definition of a regulation, and therefore the director's discretion must be exercised after the APA procedures have been satisfied.

Contrary to the Department's suggestion, this should not be an onerous requirement. As we explained in an earlier case, changes to the Medi-Cal formulary were normally accomplished by a regulation adopted in accordance with modified APA procedures, but the Legislature then created an explicit APA exemption. (Upjohn Co. v. Brewer (1990) 225 Cal.App.3d 353, 355-356, 358.) Before then the formulary was subject to the APA but was freed from some of its procedural details. (See Former Welf. & Inst. Code, §§ 14105.4, subd. (d), 14105.41; Stats. 1985, ch. 693, §§ 1-2, p. 2304 and Stats. 1989, ch. 689, § 1, p. 2261.) Thus, the Legislature previously treated the Medi-Cal formulary as a "regulation" under the APA, albeit one blessed with special treatment. As the trial court noted, by subsequent legislation, APA compliance is no longer required for changes to the Medi-Cal formulary. (Welf. & Inst. Code, § 14105.39, subd. (g).) But absent this exemption, the formulary would be a regulation. the Department becomes burdened by APA compliance as to the ADAP formulary, it is free to seek another legislative exemption.

Savient is entitled to a writ of mandate compelling the Department to vacate the decision to delist Oxandrin and a declaration that the formulary and any future changes must be promulgated in compliance with the APA procedures. Savient does not seek, and common sense does not compel, an order impairing the ADAP program, on which 27,000 Californians depend, until APA compliance is achieved. Except for relisting of Oxandrin, the Department may implement the formulary pending APA compliance.

## IV. Right to a Due Process Hearing

Savient asserts the partial delisting of Oxandrin was arbitrary and capricious. If a regulation is adopted without APA compliance, there is rarely a record on which to judge the regulation. (See California Optometric Assn. v. Lackner (1976) 60 Cal.App.3d 500, 506, 510-511; California Assn. of Nursing Homes, etc., Inc. v. Williams (1970) 4 Cal.App.3d 800, 810-812 (CANH).) Apart from APA compliance, which will provide a form of hearing, Savient asserts it is entitled to due process hearing rights.

The trial court found that Savient had no due process right to a trial-like hearing:

"Due process rights attach only to recognized liberty or property interests. [Citation.] Petitioner has not established that it has any such interest in the continued, unrestricted availability of Oxandrin through the ADAP formulary. Instead, petitioner's interest is, at most, analogous to that of a Medi-Cal provider in its continued participation in the program. It has been held consistently that such interest is not a protected one entitled to full due process protections."

Savient asserts that "courts have long held that changes in the status quo which effect one's business are vested fundamental rights entitled to due process protection, and subject to the independent judgment of reviewing courts."

Without analysis Savient string-cites cases which involve significant impairments of rights. (E.g., Berlinghieri v. Department of Motor Vehicles (1982) 33 Cal.3d 392 [driver's license]; Anton v. San Antonio Community Hosp. (1977) 19 Cal.3d 802 [hospital privileges] Strumsky v. San Diego County Employees

Retirement Assn. (1974) 11 Cal.3d 28 [death allowance].) They do not support Savient's view that any impact on one's business constitutes an impairment of a vested right.

The future right to supply products pursuant to a government program is not a fundamental vested right. (See Lin v. State of California (2000) 78 Cal.App.4th 931, 935; Bergeron v. Department of Health Services (1999) 71 Cal.App.4th 17, 22-23.) Savient is not compelled to participate in the ADAP program and thus has not suffered an impairment of its liberty interests. (See Zimmerman v. Brian (1974) 41 Cal.App.3d 563, 568; CANH, supra, 4 Cal.App.3d at pp. 816-817.)

## V. Rebate Structure

Savient heads one argument that respondents "have a duty to negotiate" rebates and another that the "collection of rebates is illegal absent a contractual basis." Savient makes assertions about the rebate structure, but absent adequate supporting citations or legal argument we decline to address them. (People v. Turner (1994) 8 Cal.4th 137, 214, fn. 19; In re Marriage of Nichols (1994) 27 Cal.App.4th 661, 672, fn. 3.) Savient then states it "is not alleging, or even inferring, that there have been improprieties. The objection is that Respondents' operation of the ADAP program in a secret fashion makes it impossible to determine the criteria upon which decisions are made to add or delete various drugs to or from the" formulary. This appears to be an iteration of the claim that the formulary was improperly changed. That will be explored in the APA process.

VI. New Issues in the Reply Brief
Savient raises new issues in the reply brief. Because
respondents have not had an opportunity to reply to these
belated claims, we decline to address them. (Kahn v. Wilson
(1898) 120 Cal. 643, 644.)
DISPOSITION
The judgment is reversed with directions to issue a
judgment consistent herewith. Savient and the Department shall
bear their own costs on appeal, but Savient shall pay Ramsell's
costs. (Cal. Rules of Court, rule 8.276(a)(3)(4).)
MORRISON, J.
We concur:

DAVIS , Acting P.J.

HULL , J.